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09/867,845	05/29/2001	Chaitan Khosla	300622005500	7453
82359 7590 08/11/2009 Bristol-Myers Squibb Company c/o MoFo 12531 High Bluff Drive, Ste. 100 San Diego, CA 92130				
EXAMINER				
ZHOU, SHUBO				
ART UNIT		PAPER NUMBER		
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

09/867,845

**Applicant(s)**

KHOSLA ET AL.

**Examiner**

SHUBO (Joe) ZHOU

**Art Unit**

1631

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 14-19 and 21-28 is/are pending in the application.
- 4a) Of the above claim(s) 25-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-19 and 21-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's amendment and request for reconsideration filed 5/6/09 are acknowledged and the amendment is entered.

Newly added claims 25-28 are drawn to an invention that is distinct from the elected and examined invention. The elected and examined invention is drawn to a method, e. g. in claim 14, where a polyketide molecule is produced as an end of product whereas the claims are drawn to a PKS gene produced by a method of claim 14, etc., which do not produce a PKS gene. Thus the inventions are distinct. Claims 25-28 are thus withdrawn from further consideration.

#### ***Status of the Claims***

Claims 14-19 and 21-28 are pending.

Claims 25-28 are withdrawn from further consideration.

Claims 14-19 and 21-24 are under consideration.

#### ***Specification***

The specification is objected to because of the following including informalities:

The phrase "there as been considerable interest ..." recited in line 5 of page 2 of the specification appears to be a typographical error. Is ""there has been considerable interest ..." intended?

Appropriate correction is requested.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The rejection of claims 14-19 and 21-23 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter set forth in the previous Office action has been withdrawn in view of the amendment filed 5/6/09, where the claims are amended to accomplish a physical transformation in producing the desired polyketide.

Claim 24 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The rejection is necessitated by applicant's amendment to the claim filed 5/6/09.

The claim is drawn to a computer readable medium embodying a computer program. While the instant specification does not explicitly define the scope of the limitation of "computer readable medium," one skilled in the art would understand that computer readable medium includes carrier wave, which is a signal. For example, Fiekowsky et al., in US patent 6,090,555 (Date of Patent: July 18, 2000), define computer readable medium as being "a CD-ROM, floppy disk, tape, flash memory, system memory, hard drive, and a data signal embodied in a carrier wave." See column 14, claim 12. Bornstein et al., in US patent 6,144,388 (Date of patent : Nov. 7, 2000) state, "The computer readable medium of the present invention generally includes a tape, a floppy disk, a CD ROM, a carrier wave. In a preferred embodiment, however, the computer readable medium of the present invention is a carrier wave." See column 8, lines 33-37.

Therefore, at least one embodiment of the instant claim is drawn to carrier wave or a signal encoded thereon a computer program.

It was held by the court that claims that recite nothing but the physical characteristics of a form of energy, such as a frequency, voltage, or the strength of a magnetic field, define energy or magnetism, per se, and as such, are nonstatutory natural phenomena. O'Reilly, 56 U.S. (15 How.) at 112-14. Moreover, it does not appear that a claim reciting a signal encoded with functional descriptive material, e.g. a computer program, falls within any of the categories of patentable subject matter set forth in § 101. See the US PTO's "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility," which is available in its website [www.uspto.gov](http://www.uspto.gov).

***Claim Rejections-35 USC § 112***

The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-19 and 21-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is reiterated from the previous Office action.

Independent claims 14, 18, and 19 are amended to recite “wherein the database comprises at least one second string of alphanumeric symbols representing a known polyketide, and wherein each alphanumeric symbol in the second string represents a monomer unit of the known polyketide.” A review of the specification reveals that it does not adequately disclose that each alphanumeric symbol in the second string in a database represents a monomer unit of a known polyketide.

Applicant’s arguments filed on 5/6/09 have been fully considered but they are not persuasive. Applicant argues that the specification such as in “paragraph [0022] describes the generating of the second string. Specifically, it is described how “[t]his aspect of the invention is directed to the design and specification of PKS genes via the recombining of modules or portions of modules or sets of modules from already known and available PKS genes. In one mode, all possible PKS genes encoding a desired polyketide from a set of genes in a database are generated,” etc. See page8-9 of the 5/6/09 response. This is not persuasive because while what the specification seems to disclose that the database comprises modules or portions of known PKS genes, which encode PKS enzymes for the synthesis of polyketide, the specification does not disclose that the database comprises string of alphanumeric symbols representing a known polyketide, and each alphanumeric symbol in the string represents a monomer unit of the known polyketide. It is noted that PKS gene encodes the PKS enzyme that catalyzes the synthesis of polyketide. Thus, disclosing structure of the PKS genes would not be an adequate disclosure of the structure of the polyketide.

With regard to the new matter in the added limitation “generating an alignment, wherein the alignment consists of a combination of common alphanumeric symbols identified from the

database such that the sequence of alphanumeric symbols in the alignment matches the first string, and wherein the alignment represents the structure of a new PKS gene capable of producing the desired polyketide," applicant's argument is moot in view of the 5/6/09 amendment where "the alignment consists of" is deleted.

The claims are amended in the 5/6/09 amendment to recite "using the third string representing the PKS gene to produce the desired polyketide." Applicant pointed to paragraphs 5, 9, 17, 22, and 23 for support therefor. However, a review of these paragraphs and the entire specification does not reveal an adequate description in the specification for the new limitation. The specification appears to describe throughout how to design and produce a PKS gene, which encodes a PKS enzyme. As is indicated in the summary paragraph on the last page (40) of the specification, "the present invention provides a useful means to generate new PKS genes and corresponding enzymes to produce polyketides." Thus, what are disclosed are methods to produce PKS genes or PKS enzymes. The specification does not adequately disclose producing the polyketides themselves.

Claim 24 is amended to recite a computer readable medium comprising a set of computer program instructions configured to enable a computer to perform the method steps of claim 14. A review of the specification does not reveal any computer instructions for producing polyketide, which is step (f) of claim 14.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-19 and 21-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preambles of independent claims 14 and 19 recite a "method of designing and producing a polyketide synthase (PKS) gene, but the claims do not actually produce the PKS gene.

The first and second strings in steps (a) and (b) both represent known polyketide, and the common symbols between the first and second strings identified in step (c) therefore should represent the monomer units of polyketide. However, the third string generated in step (d), which comprises the common symbols identified in step (c), represents the structure of a PKS gene. It is unclear as to how a string comprising the common symbols of two strings that represent polyketide could represent a PKS gene, which encodes a PKS enzyme that catalyzes the synthesis of polyketide.

### ***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. §1.136 (a). A shortened statutory period for response to this final action is set to expire three months from the date of this action. In the event a first response is filed within two months of the mailing date of this final action and the advisory action is not mailed until after the end of the three-



month shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. §1.136 (a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than six months from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/SHUBO (Joe) ZHOU/

Shubo (Joe) Zhou, Ph.D.

Primary Examiner

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